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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

In re RIGEL PHARMACEUTICALS, INC. ) No. 3:09-cv-00546-JSW  
SECURITIES LITIGATION )  
CLASS ACTION

This Document Relates To: ) PLAINTIFF'S OPPOSITION TO RIGEL  
AND INDIVIDUAL DEFENDANTS'  
ALL ACTIONS. ) MOTION TO STRIKE DECLARATION OF  
DANIEL A. BLOCH AND UNDERWRITER  
DEFENDANTS' JOINDER THERETO

DATE: April 9, 2010  
TIME: 9:00 a.m.  
COURTROOM: The Honorable  
Jeffrey S. White

1 **I. INTRODUCTION<sup>1</sup>**

2 The Declaration of Daniel A. Bloch (“Bloch Declaration”), attached as Ex. A to the  
 3 Consolidated Amended Complaint for Violations of the Federal Securities Laws, dated January 27,  
 4 2010 (“CAC”) (Doc. 59) and incorporated therein, sets forth particularized facts, on which certain of  
 5 plaintiff’s allegations regarding false and misleading statements are premised, satisfying the  
 6 heightened pleading standards of the Private Securities Litigation Reform Act of 1995 (“PSLRA”)  
 7 and Fed. R. Civ. P. 9(b). Dr. Bloch is a Professor (Emeritus) of Biostatistics at Stanford University,  
 8 an author or co-author of 196 original articles and a statistical peer reviewer for dozens of major  
 9 journals, including *Arthritis and Rheumatism*. Bloch Declaration at 1. Dr. Bloch’s declaration  
 10 explains why purportedly positive efficacy results of the Phase IIa RA clinical trial, reported  
 11 publicly, were false and misleading. In a motion to strike, “[t]he court may strike from a pleading an  
 12 insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ.  
 13 P. 12(f). However, “[i]mmaterial matter ‘is that which has no essential or important relationship to  
 14 the claim for relief or the defenses being pleaded.’” *Z.A. v. St. Helena Unified Sch. Dist.*, No.  
 15 C 09-03557 JSW, 2010 U.S. Dist. LEXIS 12858, at \*5-\*6 (N.D. Cal. Jan. 25, 2010) (citation  
 16 omitted). Motions to strike are regarded with disfavor because they are often used as delaying  
 17 tactics. *Id.* at \*6. When there is any doubt as to the relevance of the allegations, courts generally err  
 18 on the side of permitting the allegations. *Id.* Dr. Bloch’s declaration has an “essential and important  
 19 relationship” to plaintiff’s allegations as it forms “information and belief” on which certain  
 20 allegations in the CAC are based. Furthermore, contrary to defendants’ assertion, under this  
 21 Circuit’s law and the Federal Rules of Civil Procedure, the Bloch Declaration can be considered as  
 22 part of the CAC in deciding defendants’ motion to dismiss.

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 26 <sup>1</sup> This opposition also addresses Underwriter Defendants’ Notice of Joinder and Joinder in  
 27 Rigel and Individual Defendants’ Motion to Strike Declaration of Daniel A. Bloch, dated February  
 28 16, 2010 (Doc. 69). All “Doc.” references are to the Court’s Electronic Case Filing system.

## II. ARGUMENT

The PSLRA and Fed. R. Civ. P. 9(b) require plaintiff to plead particular facts in the complaint. Under the PSLRA, actions based on allegations of material misstatements or omissions must “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.” 15 U.S.C. §78u-4(b)(1); Order Granting Defendants’ Motion to Dismiss, dated December 21, 2009 (Doc. 55) at 9. Plaintiff incorporated and attached the Bloch Declaration to the CAC to provide particularly with the “information and belief” on which plaintiff makes allegations regarding certain of defendants’ false and misleading statements. In deciding defendants’ motion to dismiss, “[t]he Court may consider facts alleged in the complaint, documents attached to the complaint, documents relied upon but not attached to the complaint when the authenticity of those documents is not questioned, and other matters for which the Court can take judicial notice.” *Id.* at 8 (citing *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009)).

Here, the Bloch Declaration provides a basis for plaintiff’s allegations with respect to how and why the results of the Phase IIa RA clinical trial of R788 were not statistically significant as reported by defendants. Dr. Bloch is a highly respected Stanford University Professor (Emeritus) of Biostatistics with particular experience in applying statistics to the rheumatic diseases, including rheumatoid arthritis. Bloch Declaration at 1. Dr. Bloch has authored or co-authored 196 articles in peer-reviewed journals, including more than 30 articles in *Arthritis and Rheumatism* – the same journal in which defendants’ November 2008 article appeared. *Id.* Dr. Bloch has served as a statistical-reviewer for dozens of medical journals including most journals in the U.S., Canada and Europe that specialize in arthritis and rheumatism. *Id.*

The Bloch Declaration explains the details behind why defendants’ statements as to the efficacy of R788 were false and misleading, including that the results of the Phase II RA clinical trial did not demonstrate that R788, at the 100mg and 150mg doses at ACR 20, the primary efficacy endpoint, *were not statistically significant* under the application of basic statistical analysis. *Id.* at 6, 12-13. Dr. Bloch looked at the results of the R788 Phase II RA clinical trial (not known to investors

in December 2007, February 2008 or July 2008), set forth the principles of basic statistics and then elaborated on the violations of those basic statistical principles to the results defendants had prior to the Class Period. Indeed, he explained that, *inter alia*, basic statistics required that the clinical trial result data be analyzed separately to account for the multisites (U.S. and Mexico) and that two p-values be calculated. *Id.* at 5-6. The pooling of the U.S. and Mexico data, as defendants did, “resulted in misleading success rates and false p-values.” *Id.* at 5. Dr. Bloch also explained that under statistical principles, defendants’ use of the chi-squared analysis was inappropriate because of the small sample size of the Phase IIa RA clinical trial. *Id.* at 7-9. The result of defendants’ violation of statistics was that R788 appeared to exhibit greater statistical significance than supported by the actual results of the study. *Id.* at 6-7. Further, Dr. Bloch set forth the requirement under proper statistical analysis to account for multiple pair-wise comparisons (*i.e.*, 100mg versus placebo at ACR20, 100mg versus placebo at ACR50, 100mg versus placebo at ACR70) when analyzing clinical trial results and explained why defendants’ failure to follow this basic statistical principal rendered their statements misleading as to the efficacy of R788. *Id.* at 3-4, 6, 11-12. The Bloch Declaration details why the publicly announced results of the Phase IIa RA clinical trial were false and misleading: The results were neither “statistically significant,” “impressive,” a “major milestone” nor did they demonstrate that R788 was “highly effective” as defendants led investors to believe. ¶¶6, 74-90.<sup>2</sup>

In addition, the Bloch Declaration is part of the CAC. The United States Court of Appeals for the Ninth Circuit held that attachments to a complaint are to be considered part of the complaint in deciding a Rule 12(b)(6) motion. *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1062 (9th Cir. 2004) (citing *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989)). Similarly, if a complaint refers to a document, that document becomes part of the complaint. “[A] document is not ‘outside’ the complaint if the complaint specifically refers to the document and if its authenticity is not questioned.” *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir.

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<sup>2</sup> All paragraph (“¶”) references are to the CAC.

1994) (citing *Townsend v. Columbia Operations*, 667 F.2d 844, 848-49 (9th Cir. 1982)). “When a plaintiff has attached various exhibits to the complaint, those exhibits may be considered in determining whether dismissal was proper without converting the motion to one for summary judgment.” *Park Sch. of Bus. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995) (citing *Cooper v. Bell*, 628 F.2d 1208, 1210 n.2) (9th Cir. 1980)); *see also Greetis v. Nat’l City Mortgage*, No. 09 CV 1502 JM (JMA), 2010 U.S. Dist. LEXIS 16354, at \*5 (S.D. Cal. Feb. 24, 2010); *Aleem v. Bank of Am.*, No. EDCV 09-01812-VAP (RZx), 2010 U.S. Dist. LEXIS 11944, at \*5-\*6 (C.D. Cal. Feb. 9, 2010).

Contrary to defendants’ assertion, most courts agree that Fed. R. Civ. P. 10(c) provides that all attached exhibits become part of the complaint. *See Plantronics, Inc. v. Am. Home Assurance Co.*, No. C 07-6038 PVT, 2008 U.S. Dist. LEXIS 88921, at \*2 (N.D. Cal. Oct. 20, 2008) (under Fed. R. Civ. P. 10(c), “[a] copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes.”); *Hypolite v. Cal. Dep’t of Corr.*, No. CIV S-05 0428 MCE DAD P, 2008 U.S. Dist. LEXIS 83089, at \*7 n.3 (E.D. Cal. Sept. 8, 2008) (per Fed. R. Civ. P. 10(c), “exhibits appended to a complaint are considered a part thereof for all purposes.”); *Aquair Ventures, LLC v. Gulf Stream Coach, Inc.*, No. C-08-2903 SC, 2008 U.S. Dist. LEXIS 78811, at \*3 (N.D. Cal. Sept. 4, 2008) (according to Fed. R. Civ. P. 10 (c), “where another document is attached to the complaint . . . the court may treat that document as part of the complaint and consider it when ruling on a motion to dismiss”); *Picon v. County of San Mateo*, No. C-08-766 SC, 2008 U.S. Dist. LEXIS 111416, at \*6 (N.D. Cal. July 10, 2008) (same).

Affidavits attached to the complaint are considered to be part of the complaint. *Gulden v. Geren*, No. CV 08-1805-PHX-NVW, 2009 U.S. Dist. LEXIS 55844, at \*2 (D. Ariz. June 16, 2009) (the court considered plaintiff’s attached affidavit exhibit as part of the complaint). Other circuits have held the same. In *In re Resource Am. Sec. Litig.*, the court sustained plaintiffs’ complaint in part on the basis of statements in “affidavits by two of plaintiffs’ financial experts” which plaintiffs “[a]ttached to the Amended Complaint,” in which the experts opined that defendant Resource America’s public disclosures were “‘improper’” and “‘subject to misinterpretation by shareholders.’” No. 98-5446, 2000 U.S. Dist. LEXIS 10640, at \*14 (E.D. Pa. July 26, 2000) (citation omitted); *see*

1 *also Amini v. Oberlin Coll.*, 259 F.3d 493, 502 (6th Cir. 2001) (exhibits attached to the complaint  
 2 should be taken into account on a Rule 12(b)(6) motion); *Northern Ind. Gun & Outdoor Shows v.*  
 3 *City of S. Bend*, 163 F.3d 449, 453 (7th Cir. 1998) (“this Court has interpreted the term ‘written  
 4 instrument’ as used in Rule 10(c) to include documents such as affidavits”) (citing *Schnell v. City of*  
 5 *Chicago*, 407 F.2d 1084, 1085 (7th Cir. 1969); *Olson v. Brown*, No. 4:09-cv-00006-AS-PRC, 2009  
 6 U.S. Dist. LEXIS 52772, at \*6 (N.D. Ind. June 22, 2009) (same)).

7 The main case upon which defendants rely, *DeMarco v. Depotech Corp.*, 149 F. Supp. 2d  
 8 1212 (S.D. Cal. 2001), is not controlling and inapposite. While the court in *DeMarco* granted a  
 9 motion to strike an expert affidavit, it did so on a limited basis and through a narrow interpretation of  
 10 the Federal Rules of Civil Procedure. The *DeMarco* court took the position that the affidavit did not  
 11 qualify as a “written instrument” under Fed R. Civ. P. 10(c), citing a district court case, *Murphy v.*  
 12 *Cadillac Rubber & Plastics*, 946 F. Supp. 1108 (W.D.N.Y. 1996), and a case from the United States  
 13 Court of Appeals for the Third Circuit, *Rose v. Bartle*, 871 F.2d 331 (3d Cir. 1989). *DeMarco* at  
 14 1220. In both cases, *Murphy* and *Rose*, the types of affidavits in issue were plaintiffs’ own  
 15 supporting statements, not an expert declaration. *Murphy*, 946 F. Supp. at 1115; *Rose*, 871 F. 2d at  
 16 340 n.3. However, as shown above, within the Ninth Circuit, courts and others have considered  
 17 documents attached to the complaint, including affidavits, to be part of the complaint.

18 Moreover, the *DeMarco* court specifically noted that it did review the affidavit in assessing  
 19 the pleadings and concluded that it did not “[bring] the Second Amended Complaint into compliance  
 20 with the Reform Act or Rule 9(b).” *Id.* at 1222 n.5. Additionally, the court there denied the  
 21 defendants’ motion to strike “to the extent it seeks an order striking those portions in the Second  
 22 Amended Complaint that were derived from the Makuch affidavit.” *Id.* at 1222. Thus, the portions  
 23 of the affidavit alleged in the complaint were allowed to stand. *Id.* Accordingly, defendants’ motion  
 24 is of little consequence because plaintiff has incorporated the main findings of the Bloch Declaration  
 25 into the CAC, and the Ninth Circuit credits expert analysis in assessing claims of the violations of  
 26 the securities laws. *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1233  
 27 (9th Cir. 2004) (the court considered and credited plaintiffs’ expert witness’ finding at the pleading  
 28 stage – a statistical expert whose calculations were incorporated in plaintiffs’ complaint).

1 The Bloch Declaration is properly considered part of the CAC as it is a written instrument  
2 under Fed. R. Civ. P. 10(c), has been extensively incorporated in the CAC and is thus relevant to the  
3 allegations. However, if for any reason the Court decides to strike the Bloch Declaration, it should  
4 only strike the attachment (Ex. A) to the CAC, not the allegations in the CAC that refer to the  
5 declaration.

6 **III. CONCLUSION**

7 For the foregoing reasons, defendants' motion should be denied.

8 DATED: March 8, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I further certify that I caused this document to be forwarded to the following Designated Internet Site at: <http://securities.stanford.edu>.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on March 8, 2010.

/s/

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